

Appl. No. 10/580,232
Amendment dated: December 4, 2009
Reply to OA of: September 2, 2009

REMARKS

This is in response to the Official Action dated September 2, 2009, in connection with the above identified application. Applicants have amended claim 32 to remove the extra period at the end of the claim as noted by the Examiner in the Official Action. This amendment obviates the objection to claim 32 and it is most respectfully requested that this objection be withdrawn. New claims 33 and 34 are directed to further aspects of the kit as fully supported by the specification as originally filed, see especially, the first paragraph on page 9 of the specification. Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The Official Action states that the independent claims 1 and 26 are obvious based on the document WO 00/43774 (Willner) in view of US 4,128,628 (Brooker). The Official Action concludes that Willner discloses a competition immunoassay but acknowledges that the reference does not teach a mixture of at least two different unlabeled antibodies as required by the claims present in this application. Applicants agree with this statement.

According to the Official Action, Brooker describes an immunoassay that uses a mixture of two or more different antibodies, in order to perform a multiplexed assay for simultaneous detection of different antigens. This statement is based on the disclosure in column 3, lines 50-60: column 7, lines 32-35 of the reference.

At column 3, lines 50-60 in the specification, it states:

"In accordance with the present embodiment of this invention, immunoassay of a multiplicity of samples is achieved. The sample which is suspected to contain an antigen, or an antibody to be assayed, is first mixed with a solution of a detectable antigen or antibody. The antigen or antibody can be made detectable by reacting a detectable ligand therewith, such as a radioactive isotope, a fluorescent compound, a luminescent compound, a bioluminescent compound, an

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enzyme, another antibody, or another antibody, or by a variety of known techniques.”

At column 7, lines 32-35, the specification states:

“Instead of a single antibody or a single antigen, a plurality of different antigens or antibodies can be simultaneously assayed by using two or a plurality of different tagged antigens or tagged antibodies.”

Thus, at column 3, the reference teaches that immunoassay of a multiplicity of samples (i.e. plural sample) is achieved. The sample (i.e. singular) which is suspected to contain an antigen or an antibody to be assayed (e.g. a single), is first mixed with a solution (i.e. single solution) of a detectable antigen or antibody (i.e. a single). But there is no mentioning of any mixture of two different antigens or two different antibodies in the same solution.

Column 7 implies that a plurality of different antigens or antibodies can be simultaneously assayed by using two or a plurality of different tagged antigens or tagged antibodies. There is no mentioning of different antigens or antibodies in the same solution as in the present invention.

Guidance for the interpretation of the two cited passages is found in the Brooker patent e.g. in column 9, lines 4 – 8 “The flexibility of this system is quite excellent and the system may be used for continuous assay of different antibody-antigen systems. Thus, each sample solution extracted and introduced into conduit 13 may contain a different antigen-antibody system.” and in Example 7, column 14, lines 60-66 “The automated radioimmunoassay system of the present invention is especially versatile being able to alternately sequentially assay for different substances. The following nine substances at the concentrations indicated were placed in the sampler tray and their respective isotope solutions were drawn as each sample was processed.”

Thus, the substances were placed in a sampler tray and were mixed with their respective isotope solutions as each sample was processed. There is no suggestion of having a mixture of different antibodies or different antigens in the same solution, and further, as noted by the Examiner, Brooker used labeled molecules for detection.

In conclusion, neither Willner nor Brooker alone or a combination thereof teaches or suggests a mixture of isolated or synthetic unlabelled affinity molecules in a liquid carrier comprising at least two different affinity molecules, each with affinity for a predetermined analyte, for use in a single or multi flow cell piezoelectric crystal micro balance apparatus in accordance with the present invention. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

With respect to the obviousness rejection of claims 2-5, 16, 25 and 27-32, it is again noted that the antigen or antibody of Booker et al is labeled while the mixture of isolated or synthetic unlabeled affinity molecules has no label in accordance with the presently claimed invention. Moreover, the concentrations used in the present invention provide results which are not simply the result of routine optimization as there is nothing to suggest the mixture of unlabeled affinity molecules in accordance with the present invention.

In the first full paragraph on page 5 of the rejection, it is stated that the facts of Aller are relevant here. Similar to that case, Willner and Brooker teach all the limitations of claims 4 and 28 except for the specific concentration range. This statement is specifically traversed since as noted above, there is no teaching of the unlabeled affinity molecules in Brooker and therefore the combination of references does not teach all of the limitations in claims 4 and 28.

Regarding claims 5, 27 and 32, Willner is said to describe antibodies diluted in PBS with reference to page 21, line 8. This portion of the reference relates to a binding assay for anti-TNT antibodies where microtiter plates were coated with antigen by incubating them with the antigen in PBS for at least two hours at room temperature. However, this does not suggest the necessary modifications to the prior art to arrive at the presently claimed invention. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

With respect to claim 16, there is absolutely no suggestion of a kit in accordance with presently claimed invention in the Willner and Brooker references for the reasons discussed above. Please also note the additional kit claims including those in which claim a combination of affinity molecules specific for explosives and narcotics, thus enabling detection of both explosives and narcotics in

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one run as noted at the top of page 7 of Applicants specification. There is absolutely no suggestion of this combination in the prior art, nor is there any motivation of all rational reason in support of this rejection. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

Similarly, with respect to the rejection of claims 25, 31, 29-30, the prior art references do not overcome the deficiencies of the claims including the limitations of the prior claims and therefore it is most respectfully requested that this aspect of the rejection be withdrawn.


The rejection of claim 6 under 35 U.S.C. 103 as unpatentable over Willner and Brooker as applied to claim 1 above and further in view of the Strahilevitz patent has been carefully considered but it is most respectfully traversed. The combination of Willner and Brooker does not render obvious the presently claimed invention for the reasons discussed above. Moreover, as noted in the rejection of claim 6, there is no disclosure which teach a narcotic analyte. The Strahilevitz reference is said to describe an antibody directed to heroin, in order to detect a drug in a biological material with reference to the abstract, column 1, lines 13-15. This reference relates to immunological methods for removing species from the blood circulatory system and devices there for as stated in the title. In the abstract, it is stated that the immunoassay methods include both a agglutination and agglutination-inhibition reaction and the treatment methods include treatment of both exogenous, administrated drugs, including heroin. However, there is no suggestion of any utility of any motivation to combine this teaching with those of the primary references to arrive at the presently claimed invention. Column 1, lines 13-15 of the reference relied upon in the rejection simply states that at the present time, there are certain methods used for the determination of psycho to mimic and narcotic drugs in biological materials. The combination of references relied upon in the rejection does not render the presently claimed invention obvious to one of ordinary skill in the art. Accordingly, it is most respectfully requested that this rejection be withdrawn.

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In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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